EXHIBIT F

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
SOUTHERN DIVISION

UNITED STATES OF AMERICA)
)
Ex Rel. VEN-A-CARE OF THE)
FLORIDA KEYS, INC.)
) MAGISTRATE JUDGE GARBER
Plaintiff,)
)
v.) CIVIL ACTION NO. 95-1354 CIV - MARCUS
)
ABBOTT LABORATORIES; [redacted]) COMPLAINT AND
) DEMAND FOR JURY TRIAL FILED
) IN CAMERA AND UNDER SEAL
)
Defendants.)

COMPLAINT
FOR MONEY DAMAGES AND CIVIL PENALTIES UNDER THE FALSE CLAIMS ACT 31 U.S.C. §§3729-3732

COMES NOW, the UNITED STATES OF AMERICA ("UNITED STATES" or "GOVERNMENT"), by and through VEN-A-CARE OF THE FLORIDA KEYS, INC. ("VEN-A-CARE" or "the Relator"), and by the undersigned attorneys on behalf of the UNITED STATES and on the Relator's own behalf and brings this action against ABBOTT LABORATORIES; [redacted]

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[redacted], (sometimes referred to collectively as, "DEFENDANT DRUG MANUFACTURERS"), and other drug manufacturers not yet joined in this action, for money damages and civil penalties arising out of the DEFENDANT DRUG MANUFACTURERS' violations of the Federal False Claims Act, 31 U.S.C., §§ 3729-3732.

I.

SUMMARY OF THE ACTION

1. This is an action for damages, treble damages, civil penalties and costs against the DEFENDANT DRUG MANUFACTURERS arising from their repeated and knowing reporting of grossly inflated, false and fraudulent cost and price information regarding certain pharmaceutical products specified herein and manufactured and/or sold by them. The false and fraudulent price and cost information was knowingly reported in a manner whereby it was used by the United States Medicare program and by federally funded States' Medicaid Programs in setting reimbursement amounts paid for pharmaceuticals sold by the DEFENDANT DRUG MANUFACTURERS. As a direct and proximate result of the grossly inflated price and cost information reported by the DEFENDANT DRUG MANUFACTURERS, the Medicare and Medicaid programs set allowed charges for pharmaceuticals specified herein of the DEFENDANT DRUG MANUFACTURERS that

were many times greater than the average acquisition costs paid by the providers/suppliers for the drugs that were manufactured and/or distributed by the DEFENDANT DRUG MANUFACTURERS and many times greater than the mark-up over true cost that the Medicare and Medicaid programs intended to pay persons and entities supplying the pharmaceuticals to Medicare and Medicaid beneficiaries. For example, Defendants [redacted] falsely reported price and cost information relating to the drug [redacted] and thus caused the Medicare and Medicaid programs to pay reimbursement amounts for [redacted] which exceeded by approximately 900% a reasonable reimbursement based upon the drug's true average acquisition cost. As a direct and proximate result, the UNITED STATES sustained damages in excess of $300,000,000 for years 1993, 1994, and 1995 to date in the form of federal funds expended for excessive reimbursement for [redacted]. The DEFENDANT DRUG MANUFACTURERS knew or should have known that their false and fraudulent reports of price and cost information would cause the Medicare and State Medicaid programs to pay grossly excessive and unreasonable reimbursement for their pharmaceutical products and that said reimbursement would, in significant part, be paid by the United States Government. The Government has sustained damages in excess of TWO BILLION DOLLARS ($2,000,000,000.00) as a result of the false and fraudulent information knowingly supplied by the DEFENDANT DRUG MANUFACTURERS and other drug manufacturers not yet joined in this action. Accordingly, the United States Government is

entitled to recover treble damages in excess of SIX BILLION DOLLARS ($6,000,000,000), plus civil penalties and costs pursuant to **31 U.S.C. §3729, et. seq.**

II.

THE PARTIES

2. The Plaintiff in this action is the UNITED STATES. At all times material to this civil action, the United States Department of Health and Human Services ("HHS"), The Health Care Financing Administration ("HCFA"), and The Bureau of Program Operations ("BPO") were agencies and instrumentalities of the UNITED STATES and their activities, operations and contracts in administering the Medicare program were paid from UNITED STATES' funds. The UNITED STATES and its subcontractors performing on behalf of the UNITED STATES provided Medicare benefits to qualified beneficiaries which included reimbursement for the pharmaceuticals specified herein manufactured by the DEFENDANT DRUG MANUFACTURERS and relied upon the false and fraudulent price and cost information presented by the DEFENDANT DRUG MANUFACTURERS in setting reimbursement amounts.

3. The States, United States Territories, and the District of Columbia provided Medicaid benefits to qualified beneficiaries which included reimbursement for the pharmaceuticals manufactured by the DEFENDANT DRUG MANUFACTURERS and relied upon the false and fraudulent price and cost information presented by the DEFENDANT DRUG MANUFACTURERS in setting reimbursement amounts. A significant part of said

Medicaid reimbursement was paid from United States Government funds pursuant to **42 U.S.C. § 1396(b).**

4. The Relator, VEN-A-CARE, is a corporation organized under the laws of the State of Florida, with its principal offices in Key West, Florida. The Relator is an infusion pharmacy and provides pharmaceuticals, such as the intravenous and injectable drugs specified in this complaint, as a Medicare Part B supplier and as a Medicaid provider. The Relator has direct and independent knowledge of the information, and is the "original source" of the information on which these allegations are based within the meaning of **31 U.S.C. §3730(e)(4)(A) and (B)**. The Relator has standing to bring this action pursuant to **31 U.S.C. §3730(b)(1)**. The information upon which these allegations are based was voluntarily provided by the Relator to the Federal Government and States beginning in 1991 and thereafter has been frequently supplemented by the Relator.

5. The Defendant, ABBOTT LABORATORIES ("ABBOTT"), is a corporation organized under the laws of Illinois with its principal offices in Abbott Park, Illinois. At all times material to this civil action, ABBOTT has transacted business in the federal judicial district of the Southern District of Florida by, including but not limited to, selling and distributing pharmaceutical products to purchasers within the Southern District of Florida.

6. [redacted]

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[redacted]

7. [redacted]

[redacted]

8. [redacted]

[redacted]

9. [redacted]

[redacted]

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10. [redacted]

11. [redacted]

12. [redacted]

13. [redacted]

14. [redacted]

15. [redacted]

16. The Defendants specified in paragraphs 5 through 15 are sometimes referred to herein collectively as the "DEFENDANT DRUG MANUFACTURERS". Any and all acts alleged herein to have been committed by each of the DEFENDANT DRUG MANUFACTURERS were committed by said Defendant's officers, directors, employees, or agents who at all times acted on behalf of their respective DEFENDANT DRUG MANUFACTURER.

III.

JURISDICTION & VENUE

17. Jurisdiction is founded upon the **Federal False Claims Act, 31 U.S.C. §3729-32**, specifically **31 U.S.C. §3732**, and also **28 U.S.C. §§1331, 1345**.

18. Venue in the Southern District of Florida is appropriate under **31 U.S.C. §3732(a)** in that each of the DEFENDANT DRUG MANUFACTURERS transacted business in the Southern District of Florida by selling directly or through wholesalers pharmaceutical products in the Southern District of Florida which the respective Defendants knew would be supplied to Medicare and Medicaid beneficiaries and for which the DEFENDANT DRUG MANUFACTURERS knew that grossly excessive and unreasonable reimbursement would be paid to the providers/suppliers by the Medicare and Medicaid programs.

19. A copy of this Complaint and written disclosure of substantially all material evidence and information The Relator possesses have been served on the Government pursuant to **Rule 4(l), Fed.R.Civ.P.**, prior to the filing of this Complaint in camera and under seal by delivering a copy of the summons, Complaint, material evidence and information to the United States Attorney for the Southern District of Florida and by sending a copy of the summons, Complaint, material evidence and information by certified mail to the Attorney General of the United States at Washington, District of Columbia.

20. The Relator alleges, based on information and belief: (A) that no allegation or transaction of defrauding the United States was made prior to the filing of this Complaint

in public disclosures regarding the subject matter herein against any of the DEFENDANT DRUG MANUFACTURERS; (B) that none of the DEFENDANT DRUG MANUFACTURERS was named in public disclosures made prior to the filing of this Complaint regarding the subject matter herein; and (C), if the Court makes a finding against the Relator as to the allegations set forth in (A) and/or (B), that the Relator has direct and independent knowledge of the information on which these allegations are based within the meaning of **31 U.S.C. §3730(e)(4)(A)** and **(B)** and has voluntarily provided the information to the Government before filing this Complaint which is based on the information provided by the Relator to the Government.

IV.

BACKGROUND OF HOW UNITED STATES MONEYS ARE PAID FOR PHARMACEUTICALS UNDER "PART B" OF THE MEDICARE PROGRAM AND THE MEDICAID PROGRAM

21. As one of its functions, HHS, through HCFA, provides health insurance benefits to aged and disabled Americans pursuant to the provisions of the Medicare program, **Title XVIII of the Social Security Act, 42 U.S.C. §1395 et seq**.

22. The Medicare program provides covered health care benefits to certain targeted populations such as those persons who are over age 65, persons who are disabled, and persons who have end stage renal disease ("ESRD").

23. The Medicare program is divided into two distinct parts: (A) Medicare Part A (Hospital Insurance for the Aged and Disabled) covers services and goods furnished by

hospitals, home health agencies, hospices, and skilled nursing facilities; and (B) Medicare Part B (Supplementary Medical Insurance for the Aged and Disabled) covers physician services, and a range of other noninstitutional services, such as durable medical equipment ("DME"), oxygen concentrators, diagnostic laboratory tests, X-rays, and certain limited pharmaceutical products and supplies.

24. The United States Government partially funds state sponsored medical assistance programs for the poor pursuant to **Title XIX of the Social Security Act** through federal matching payments which includes a minimum of fifty percent (50%) for covered prescription drugs. **42 U.S.C. § 1396 et seq**.

25. The States, United States Territories and the District of Columbia are required to implement a State Health Plan containing certain specified minimum criteria for coverage and reimbursement in order to qualify for federal matching funds for Medicaid expenditures. **42 U.S.C. §1396a(a)(30)(A)**.

26. State Health Plans must, in part, provide for reimbursement for prescription drugs pursuant to a formula approved by the Secretary of HHS which determines maximum allowable reimbursement charges as a percentage of the suppliers' estimated Average Acquisition Cost ("AAC") determined for each drug manufactured by each manufacturer whose prescription drugs qualify for Medicaid reimbursement.

27. This case focuses on those pharmaceuticals that are covered under Part B of the Medicare program and under the states' Medicaid programs which are sold and distributed by the DEFENDANT DRUG MANUFACTURERS and for which the Medicare

Part B carriers and states' Medicaid Programs rely on average wholesale price ("AWP") and AAC data reported by the drug manufacturers and distributors in order to establish reimbursement amounts.

28. HCFA administers the Medicare program. HCFA awards cost-reimbursement contracts to private companies to evaluate and to process Medicare beneficiaries' claims for payment on behalf of HCFA. Under Part A, HCFA refers to contractors as "intermediaries". Under Part B, HCFA refers to contractors as "carriers." Under Part B, HCFA pays the carriers to process claims for covered benefits supplied to eligible beneficiaries and to make payments to the suppliers or to the Medicare beneficiaries for the covered services rendered under Medicare Part B. **42 U.S.C. §1395j et seq**.

29. Congress has mandated that Medicare pay no more than eighty percent (80%) of the reasonable charge for Part B pharmaceutical claims from federal funds. **42 U.S.C. §1395(l) et seq**.

30. Part B pharmaceutical claims are submitted in one of two ways. The first is by submitting to the Part B carriers a completed (hard copy) HCFA 1500 Form. The second is through an electronic claims filing procedure whereby the same information required to be included on the hard copy HCFA 1500 Form is transmitted to the Medicare Part B carriers. Two HCFA 1500 Form versions were used during the time relevant to these proceedings. HCFA Form 1500 (1/84) was used by the Medicare program for Part B pharmaceutical claims filed on or after January, 1984. In or about December 1990, HCFA created HCFA Form 1500 (12/90) and required its use for pharmaceutical claims

submitted on or after May 1, 1992. Either HCFA Form 1500 (12/90) or HCFA Form 1500 (1/84) could be used for Part B pharmaceutical claims from December, 1990 through April, 1992.

31. Beneficiaries claims are processed by the carriers as either "assigned", those claims for which payment is made by the carrier directly to the suppler, or "unassigned", those claims for which payment is made by the carrier directly to the beneficiaries.

32. Upon information and belief, the vast majority (in excess of 90%) of pharmaceutical claims are made on an assigned basis.

33. The Medicare program requires its Part B carriers to follow applicable regulations and HCFA guidelines specified in its Medicare Medicare Part B Carriers Manual (HCFA Pub. 15) in determining reasonable reimbursement amounts for covered pharmaceuticals. Part B carriers have determined reimbursement amounts for covered pharmaceuticals at a set percentage over and above the carrier's estimate of the supplier's cost for the pharmaceuticals. (**HCFA Pub. 15, §5202**) The carriers estimate costs on the basis of the AWP of the pharmaceutical.

34. HCFA categorizes Part B covered pharmaceutical drugs by an alphanumeric code and requires its carriers to refer to such pharmaceuticals in this manner.

35. In order to estimate suppliers' costs for specific pharmaceuticals, Medicare Part B Carriers and the State Medicaid programs acquire price and cost information from entities equipped to do specialized data collection of information from which to estimate average wholesale price ("AWP") (the price charged to the supplier purchasing the drug

or supply in question) or average acquisition cost ("AAC") (the supplier's cost in acquiring the drug or supply in question).

36. Medical Economics, Inc. and the Hearst Corporation are nationally recognized companies that specialize in gathering pharmaceutical wholesale and direct price data, and publishing such information in such publications as "The Red Book" which is published by Medical Economics and "The Blue Book" which is published by the Hearst Corporation. The Hearst Corporation also, through its First Data Bank Division, provides an automated data base service containing pharmaceutical price and cost information.

37. The Relator, prior to filing this action conducted certain surveys of (1) the Medicare Part B Carriers; (2) the individual state Medicaid programs; and (3) the entities specified in the preceding paragraph that gather and report pharmaceutical price and cost information. Said surveys established:

a. That the majority of the Medicare Part B Medicare Carriers rely upon price and cost information supplied by Medical Economics ("The Red Book") in setting reimbursement amounts for pharmaceuticals.

b. That more than 90% of the individual state Medicaid programs rely upon price and cost information supplied by the Hearst Corporation's First Data Bank service in setting reimbursement amounts for pharmaceuticals.

c. That Medical Economics, Inc. and The Hearst Corporation both rely solely upon information provided by the DEFENDANT DRUG MANUFACTURERS in reporting AWPs and direct prices for the pharmaceuticals at issue in this cause.

38. HCFA and each State Medicaid program utilize National Drug Codes ("NDC") assigned by the Food and Drug Administration to identify each individual drug for each manufacturer. Estimates of AAC are made for each such NDC coded drug for each manufacturer and separate maximum allowable reimbursement rates are established for each such NDC coded drug.

39. State Medicaid programs follow a similar method to determine AACs for each drug as is followed by the Medicare Part B carriers. Unlike Part B Medicare reimbursement, however, separate maximum allowable reimbursement rates are established for each NDC coded drug.

40. The pharmaceuticals at issue in this civil action are administered intravenously or intramuscularly and are ordinarily sold by the manufacturer or wholesalers directly to specialty infusion pharmacies, such as the Relator, to physicians or outpatient clinics which then supply the drugs and related supplies to the patient. Data regarding AWP and AAC for such pharmaceuticals are collected by Medical Economics and the Hearst Corporation directly from manufacturers, such as the DEFENDANT DRUG MANUFACTURERS.

VI.

THE FRAUD SCHEME PERPETRATED BY THE DEFENDANT DRUG MANUFACTURERS ON THE MEDICARE AND MEDICAID PROGRAMS

41. Beginning on or before June 23, 1989 and continuing to date, each of the DEFENDANT DRUG MANUFACTURERS has knowingly engaged in a fraudulent course of conduct designed to cause the Medicare and Medicaid programs to reimburse providers/suppliers of their pharmaceuticals, including but not limited to those specified in this complaint in amounts that grossly exceed a reasonable reimbursement.

42. Said fraudulent course of conduct entailed intentionally reporting AWPs and AACs on an ongoing basis and failing to provide accurate information regarding AWPs and AACs for pharmaceuticals manufactured, sold and/or distributed by the DEFENDANT DRUG MANUFACTURERS.

43. The false information reported by the DEFENDANT DRUG MANUFACTURERS included AWPs and AACs that exceeded by more than one thousand percent (1,000%) for some drugs the true and correct price charged by the DEFENDANT DRUG MANUFACTURERS to suppliers purchasing the pharmaceuticals directly from the manufacturer or distributor. Such grossly and fraudulently inflated AWP and AAC information caused the Medicare and Medicaid programs to establish reimbursement rates for the pharmaceuticals at issue that grossly exceeded a reasonable reimbursement based upon a reasonably accurate estimate of AWP or AAC.

44. The grossly excessive Medicare and Medicaid reimbursement rates available to suppliers and physicians for the pharmaceuticals in question acted as an inducement to suppliers and physicians to purchase said pharmaceuticals from the manufacturers or distributors who had caused the Medicare and Medicaid programs to establish reimbursement rates enabling the supplier or physician to realize the greatest possible profit over and above the true cost of the pharmaceutical set by the manufacturer or distributor.

45. At all times material to this civil action the DEFENDANT DRUG MANUFACTURERS were well aware that their false reports of AWP and AAC were causing the Medicare and Medicaid programs to establish grossly inflated reimbursement rates for the pharmaceuticals about which the DEFENDANT DRUG MANUFACTURERS provided false information. The DEFENDANT DRUG MANUFACTURERS perpetuated their fraudulent course of conduct for the express purpose of indirectly and directly maximizing their respective economic gains on the pharmaceuticals in question and with the knowledge that fraudulent conduct would cause the Medicare and Medicaid programs to expend federal moneys in the form of grossly excessive and unreasonable reimbursement.

46. The Relator has conducted surveys of the Medicare Part B carriers and the state medicaid programs to determine whether reimbursement amounts for the pharmaceuticals at issue in this action are based upon the price and cost information reported to Medical Economics and the Hearst Corporation by the DEFENDANT DRUG

MANUFACTURERS. Each of the Medicare Part B carriers and state medicaid programs surveyed confirmed that reimbursement amounts set for the pharmaceuticals at issue in this case have, at all times material to this action, been based upon the price and cost information gathered by Medical Economics and the Hearst Corporation.

47. The Relator has conducted an investigation to verify that the Defendants knew or should have known that the price and cost information reported by them about the pharmaceuticals at issue in this case was grossly, falsely and flagrantly inflated. The Relator determined through its investigation that:

a. The DEFENDANT DRUG MANUFACTURERS each reported falsely inflated price and cost information to Medical Economics and the Hearst Corporation about the pharmaceuticals at issue in this case.

b. The true prices charged by the DEFENDANT DRUG MANUFACTURERS for the pharmaceuticals at issue in this case were far less than the false prices reported by the DEFENDANT DRUG MANUFACTURERS.

c. The DEFENDANT DRUG MANUFACTURERS each participated in the Medicaid rebate program mandated by the Omnibus Budget Reconcilliation Act of 1990 ("OBRA '90") and thus were required to pay rebates to the State Medicaid programs based upon their average price for the pharmaceuticals at issue in this case.

d. When reporting average manufacturers' prices for OBRA '90 rebate purposes, the DEFENDANT DRUG MANUFACTURERS reported prices based upon their true sales prices, demonstrating their awareness of their true sales prices. Therefore,

when it benefited the DEFENDANT DRUG MANUFACTURERS to report their true prices to cause the lowest amount of rebate to be paid by them to the states, they used their true prices.

e. When reporting prices to Medical Economics and Hearst Corporation for the pharmaceuticals at issue in this case, the DEFENDANT DRUG MANUFACTURERS falsely reported amounts far in excess of those reported for OBRA '90 rebate purposes. Therefore, when it benefited the DEFENDANT DRUG MANUFACTURERS to report highest prices to maximize the reimbursement amount for the providers/suppliers from the Medicare and Medicaid programs, they used the false and grossly inflated prices.

VII.

THE SPECIFIC FRAUDULENT ACTS AND FALSE STATEMENTS OF DEFENDANT ABBOTT

48. Beginning on or before January 1, 1993 and continuing through the present date, Defendant ABBOTT knowingly and fraudulently caused the Medicare program and the states' Medicaid programs throughout the United States and its territories to pay grossly excessive and unreasonable reimbursement for certain pharmaceuticals manufactured or distributed by Defendant ABBOTT. But for the said actions of Defendant ABBOTT and/or those persons and entities acting directly or indirectly in concert with Defendant ABBOTT, the Medicare and Medicaid programs would not have paid grossly excessive and unreasonable reimbursement for said pharmaceuticals. The actions

committed by Defendant ABBOTT that caused the Medicare and Medicaid programs to pay grossly unreasonable and excessive reimbursement included, but were not necessarily limited to, knowingly and intentionally presenting false and fraudulent price and cost information which Defendant ABBOTT knew would be relied upon by the Medicare and Medicaid programs in setting reimbursement amounts for the pharmaceuticals manufactured or distributed by Defendant ABBOTT.

49. The Relator has not yet determined all of the pharmaceuticals for which the Defendant ABBOTT published false price and cost information and has not yet determined all of the years during which such false information was published. The Relator's investigation has, however, established the specific facts alleged in the following paragraphs with respect to Defendant ABBOTT and the Relator reserves the right to amend this Complaint to add information gathered in the discovery process and through further investigation.

50. Defendant ABBOTT, knowingly and fraudulently published false prices and/or caused Medical Economics ("Red Book") and/or Hearst Corporation ("Blue Book") to publish false average wholesale prices ("AWP") and/or false direct prices ("DP") during, or immediately prior to, the years specified below with respect to the pharmaceuticals specified below. For the purposes of specificity, particularity and clarity, the said false price and cost information has been organized into a chart form for each drug in question and for each NDC Number assigned to each drug in question. The information provided under the columns for Defendant's Published Price, and Red Book and Blue Book "AWP" and

"DP" reflects the false price and cost information provided by the Defendant ABBOTT. The information under the Relator's Cost column reflects the true price that Defendant ABBOTT charged the Relator for the drug or caused another entity to charge the Relator for the drug. As a very small infusion pharmacy, the prices charged to the Relator are equal to or greater than the true average direct price and the true AWP for the drug. The following specific information reflects the false price and cost information knowingly provided by Defendant ABBOTT:

a. DRUG: SODIUM CHLORIDE 0.9%

NDC NO.: 00074158302

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK		BLUE BOOK		RELATOR'S COST
		"AWP"	"DP"	"AWP"	"DP"	
1993	$8.06			$9.12	$7.68	$1.19
1994	$8.30	$9.57		$9.57	$8.06	$1.10
1995	$8.55	$9.86		$9.86	$8.30	$1.10

NDC NO.: 00074158603

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK		BLUE BOOK		RELATOR'S COST
		"AWP"	"DP"	"AWP"	"DP"	
1993	$9.90			$11.20	$9.43	$1.19
1994	$10.20	$11.75		$11.76	$9.90	$1.08
1995	$10.51	$12.11		$12.11	$10.20	$1.08

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NDC NO.: 00074798309

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK "AWP"	RED BOOK "DP"	BLUE BOOK "AWP"	BLUE BOOK "DP"	RELATOR'S COST
1993	$8.22			$9.29	$7.83	$1.01
1994	$8.47	$9.76		$9.76	$8.22	$1.03
1995	$8.72	$10.05		$10.05	$8.47	$1.03

b. DRUG: LIPOSYN II 10%

NDC NO. 00074979021

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK "AWP"	RED BOOK "DP"	BLUE BOOK "AWP"	BLUE BOOK "DP"	RELATOR'S COST
1993	$33.18			$37.53	$31.60	$6.63
1994	$34.18	$39.40		$39.40	$33.18	$6.35
1995	$35.21	$40.59		$40.59	$34.18	$6.35

NDC NO.: 00074979001

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK "AWP"	RED BOOK "DP"	BLUE BOOK "AWP"	BLUE BOOK "DP"	RELATOR'S COST
1993	$31.29			$35.39	$29.80	$7.56
1994	$32.23	$37.19		$37.16	$31.29	$6.67
1995	$33.20	$38.27		$38.27	$32.23	$6.68

NDC NO.: 00074979003

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK "AWP"	RED BOOK "DP"	BLUE BOOK "AWP"	BLUE BOOK "DP"	RELATOR'S COST
1993	$50.64			$57.27	$48.23	$7.15
1994	$52.16	$57.88		$60.14	$50.64	$6.45
1995	$53.72	$61.94		$61.94	$52.16	$6.46

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c. DRUG: VANCOMYCIN HCL

NDC NO. 00074433201

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK "AWP"	RED BOOK "DP"	BLUE BOOK "AWP"	BLUE BOOK "DP"	RELATOR'S COST
1993	$24.72			$27.95	$23.54	$3.75
1994	$25.46	$29.35		$29.36	$24.72	$3.20
1995	$26.48	$30.23		$29.36	$24.72	$3.51

NDC NO. 00074653301

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK "AWP"	RED BOOK "DP"	BLUE BOOK "AWP"	BLUE BOOK "DP"	RELATOR'S COST
1993	$49.42			$55.90	$47.07	$7.50
1994	$50.90	$58.68		$58.69	$49.42	$6.40
1995	$52.94	$60.44		$58.69	$49.42	$7.02

d. DRUG: DEXTROSE 5% IN WATER

NDC NO. 00074152203

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK "AWP"	RED BOOK "DP"	BLUE BOOK "AWP"	BLUE BOOK "DP"	RELATOR'S COST
1993	$8.16			$9.23	$7.77	$1.20
1994	$8.40	$9.69		$9.69	$8.16	$1.14
1995	$8.65	$9.97		$9.98	$8.40	$1.14

NDC NO. 00074792209

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK "AWP"	RED BOOK "DP"	BLUE BOOK "AWP"	BLUE BOOK "DP"	RELATOR'S COST
1993	$9.01			$10.18	$8.58	$1.11
1994	$9.28	$10.69		$10.69	$9.01	$1.12
1995	$9.56	$11.02		$11.02	$9.28	$1.12

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e. DRUG: LIPOSYN II 20%

NDC NO. 00074979101

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK		BLUE BOOK		RELATOR'S COST
		"AWP"	"DP"	"AWP"	"DP"	
1993	$44.75			$50.61	$42.62	$10.01
1994	$46.09	$53.18		$53.14	$44.75	$9.58
1995	$47.47	$54.73		$54.73	$46.09	$9.58

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NDC NO. 00074979103

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK "AWP"	RED BOOK "DP"	BLUE BOOK "AWP"	BLUE BOOK "DP"	RELATOR'S COST
1993	$73.77			$83.43	$70.26	$10.91
1994	$75.98	$84.31		$87.60	$73.77	$10.36
1995	$78.26	$90.23		$90.23	$75.98	$10.36

f. DRUG: LACTATED RINGERS

NDC NO. 00074795309

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK "AWP"	RED BOOK "DP"	BLUE BOOK "AWP"	BLUE BOOK "DP"	RELATOR'S COST
1993	$10.30			$11.64	$9.81	$1.27
1994	$10.61	$12.23		$12.23	$10.30	$1.12
1995	$10.93	$12.60		$11.22	$9.45	$1.14

g. DRUG: DEXTROSE 5% WITH SODIUM CHLORIDE 0.9%

NDC NO. 00074794109

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK "AWP"	RED BOOK "DP"	BLUE BOOK "AWP"	BLUE BOOK "DP"	RELATOR'S COST
1993	$9.84			$11.12	$9.37	$1.21
1994	$10.14	$11.68		$11.68	$9.84	$1.22
1995	$10.44	$12.04		$12.04	$10.14	$1.23

h. DRUG: DEXTROSE IN WATER 50%

NDC NO. 00074151805

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK "AWP"	RED BOOK "DP"	BLUE BOOK "AWP"	BLUE BOOK "DP"	RELATOR'S COST
1993	$23.46			$26.52	$22.34	$3.12
1994	$24.16	$27.86		$27.85	$23.46	$2.87
1995	$24.88	$28.69		$28.69	$24.16	$2.88

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i. DRUG: DEXTROSE IN WATER 70%

NDC NO. 00074151905

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK		BLUE BOOK		RELATOR'S COST
		"AWP"	"DP"	"AWP"	"DP"	
1993	$29.05			$32.85	$27.67	$3.75
1994	$29.92	$34.50		$34.49	$29.05	$3.67
1995	$30.82	$35.53		$35.53	$29.92	$3.57

j. DRUG: AMINOSYN II 8.5%

NDC NO. 00074108805

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK		BLUE BOOK		RELATOR'S COST
		"AWP"	"DP"	"AWP"	"DP"	
1993	$121.85			$137.80	$116.05	$9.17
1994	$125.51	$144.69		$144.69	$121.85	$9.07
1995	$129.28	$149.04		$149.04	$125.51	$9.08

k. DRUG: AMINOSYN II 10%

NDC NO. 00074109005

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK		BLUE BOOK		RELATOR'S COST
		"AWP"	"DP"	"AWP"	"DP"	
1993	$139.00			$157.20	$132.38	$11.33
1994	$143.17	$165.06		$165.06	$139.00	$11.15
1995	$147.47	$170.01		$170.01	$143.17	$11.15

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I. DRUG: AMINOSYN II 15%

NDC NO. 00074712207

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK		BLUE BOOK		RELATOR'S COST
		"AWP"	"DP"	"AWP"	"DP"	
1993	$417.01					$56.13
1994	$429.52	$495.20		$495.18	$417.00	$38.95
1995	$442.41	$510.06		$510.04	$429.59	$38.95

51. As a direct and proximate result of the false price and cost information knowlingly provided by Defendant ABBOTT, as specified in the preceding paragraph, the United States incurred damages in excess of $1,000,000 in the form of grossly excessive and unreasonable reimbursements paid by the Medicare and Medicaid programs for the pharmaceuticals about which the Defendant provided false price and cost information.

VIII.

THE SPECIFIC FRAUDULENT ACTS AND FALSE STATEMENTS OF [redacted]

52. [redacted]

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PAGES 27 THROUGH 59

HAVE BEEN COMPLETELY REDACTED

WHICH INCLUDES THE END OF

PARAGRAPH 52

THROUGH PARAGRAPH 83

XVI.

THE DAMAGE TO THE UNITED STATES CAUSED BY THE FRAUDULENT CONDUCT OF THE DEFENDANT DRUG MANUFACTURERS

84. The Medicare and Medicaid programs reasonably relied upon the false price and cost information knowingly reported by the DEFENDANT DRUG MANUFACTURERS.

85. The Medicare and Medicaid programs' reliance on the false price and cost information was detrimental in that, as a direct and proximate result of said reliance, grossly excessive and unreasonable amounts were paid as reimbursement for the pharmaceuticals of the DEFENDANT DRUG MANUFACTURERS.

86. The Medicare and Medicaid programs intended to establish reimbursement rates based upon an estimate of the average cost of the pharmaceutical to the person or entity supplying the pharmaceutical to beneficiaries.

87. The Relator's cost for each of the pharmaceuticals at issue in this cause represents an amount equal to or greater than the true average acquisition cost of the pharmaceuticals at issue to persons and entities supplying them to Medicare and Medicaid beneficiaries.

88. The false price and cost information knowingly reported by the DEFENDANT DRUG MANUFACTURERS caused the Medicare and Medicaid programs to expend federal dollars which substantially exceeded a reasonable reimbursement for the pharmaceuticals manufactured or distributed by the DEFENDANT DRUG MANUFACTURERS.

89. The UNITED STATES has sustained damages as the direct and proximate result of the false information reported by the DEFENDANT DRUG MANUFACTURERS equal to the amount of federal dollars expended to pay reimbursements for pharmaceuticals which exceeded a reasonable reimbursement based upon average acquisition costs to suppliers of the pharmaceuticals.

90. By way of example, only, Defendants [redacted] falsely reported price and cost information relating to the drug [redacted] and thus caused the Medicare and Medicaid programs to pay reimbursement amounts for [redacted] which exceeded by approximately 900% a reasonable reimbursement based upon the drug's true average acquisition cost. As a direct and proximate result, the UNITED STATES sustained damages in excess of $300,000,000 for years 1993, 1994, and 1995 to date in the form of federal funds expended for excessive reimbursement for [redacted].

91. The total damages to the UNITED STATES in the form of federal funds expended to pay excessive reimbursement through the Medicare and Medicaid programs as a result of the acts of the DEFENDANT DRUG MANUFACTURERS exceeds $500,000,000 for the years 1993, 1994 and 1995 to date.

92. This action seeks the recovery of all damages sustained by the UNITED STATES during all years as a result of false price and cost information reported by the DEFENDANT DRUG MANUFACTURERS and other drug manufacturers not yet joined as

named defendants in this action for their pharmaceuticals consistent with the specific conduct alleged herein.

93. In the alternative, each of the DEFENDANT DRUG MANUFACTURERS and others not yet charged herein, engaged in a similar course of tortious and fraudulent conduct directed at a common victim, the United States, from on or before June 23, 1989 and continuing to the present date and accordingly each Defendant is jointly and severally liable for the combined amount of damages sustained by the United States as a result of said tortious and fraudulent conduct.

COUNT I

FALSE CLAIMS ACT; CAUSING PRESENTATION OF FRAUDULENT CLAIMS

94. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES, against the Defendants, ABBOTT LABORATORIES; [redacted], under the False Claims Act, **31 U.S.C. §§3729-3732.**

95. Plaintiff realleges and incorporates by reference paragraphs 1 through 93 as if fully set forth herein and further alleges as follows:

CASE NO._____

96. The DEFENDANT DRUG MANUFACTURERS from a date on or before June 23, 1989 to the present date, knowingly [as defined in §3729(b)] caused to be presented to officers or employees of the UNITED STATES GOVERNMENT fraudulent claims [as explained in **United States v. Neifert-White, 390 US 228, 232-233 (1968)**] for payment or approval, in that the DEFENDANT DRUG MANUFACTURERS presented to Hearst Corporation/First Data Bank and Medical Economics, false and fraudulent claims of price and cost information of the DEFENDANT DRUG MANUFACTURERS' pharmaceuticals specified herein, to cause the UNITED STATES to pay out sums of money to the providers and suppliers of the DEFENDANT DRUG MANUFACTURERS' pharmaceuticals grossly in excess of the true costs for obtaining the specified pharmaceuticals from the DEFENDANT DRUG MANUFACTURERS, resulting in great financial loss to the UNITED STATES.

97. Because of the DEFENDANT DRUG MANUFACTURERS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of two (2) billion dollars ($2,000,000,000.00), all in violation of **31 U.S.C. §3729(a)(1)**

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COUNT II

FALSE CLAIMS ACT; CAUSING FALSE STATEMENTS TO BE USED TO GET FALSE CLAIMS PAID BY THE GOVERNMENT

98. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES, against the Defendants, ABBOTT LABORATORIES; [redacted]

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[redacted], under the **False Claims Act, 31 U.S.C. §§3729-3732**.

99. Plaintiff realleges and incorporates by reference paragraphs 1 through 93 as if fully set forth herein and further alleges as follows:

100. The DEFENDANT DRUG MANUFACTURERS, from a date on or before June 23, 1989 to the present date, knowingly [as defined in **§3729(b)**] caused false statements to be used to get false claims [as explained in **United States v. Neifert-White, 390 US 228, 232-233 (1968)**] to be paid by the GOVERNMENT, in that the DEFENDANT DRUG MANUFACTURERS, caused false statements of price and cost information of the DEFENDANT DRUG MANUFACTURERS' pharmaceuticals specified herein to be used by Hearst Corporation/First Data Bank and Medical Economics to get the DEFENDANT DRUG MANUFACTURERS' false claims of price and cost information of their pharmaceuticals specified herein to be paid by the GOVERNMENT to the providers and suppliers of the DEFENDANT DRUG MANUFACTURERS' pharmaceuticals, which claims were grossly in excess of the true costs for obtaining the specified pharmaceuticals from the DEFENDANT DRUG MANUFACTURERS, resulting in great financial loss to the UNITED STATES.

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101. Because of the DEFENDANT DRUG MANUFACTURERS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of Two Billion Dollars ($2,000,000,000.00), all in violation of **31 U.S.C. §3729(a)(2)**.

COUNT III

FALSE CLAIMS ACT; CAUSING FALSE STATEMENTS TO BE USED TO CONCEAL AN OBLIGATION TO PAY MONEY TO THE GOVERNMENT

102. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES, against the Defendants, ABBOTT LABORATORIES; [redacted], under the **False Claims Act, 31 U.S.C. §§3729-3732**.

103. Plaintiff realleges and incorporates by reference paragraphs 1 through 93 as if fully set forth herein and further alleges as follows:

104. The DEFENDANT DRUG MANUFACTURERS, from a date on or before June 23, 1989 to the present date, knowingly [as defined in **§3729(b)**] caused false statements to be used to conceal an obligation to pay money to the GOVERNMENT, in that: (1) the DEFENDANT DRUG MANUFACTURERS knew that the UNITED STATES' Medicare program and the States' Medicaid programs were using the DEFENDANT DRUG

MANUFACTURERS' false claims of price and cost information presented to Hearst Corporation/First Data Bank and Medical Economics for purposes of computing formulae of average wholesale price ("AWP") and/or average acquisition costs ("AAC") to pay sums of money to the providers and suppliers of the DEFENDANT DRUG MANUFACTURERS' pharaceuticals for supplying the specified list of pharmaceuticals to Medicare and Medicaid beneficiaries; the DEFENDANT DRUG MANUFACTURERS knew that sums of money paid by the UNITED STATES and State Governments to the providers and suppliers of the DEFENDANT DRUG MANUFACTURERS' pharmaceuticals were grossly in excess of the true costs for obtaining the specified pharmaceuticals from the DEFENDANT DRUG MANUFACTURERS; the DEFENDANT DRUG MANUFACTURERS knew the obligation of the UNITED STATES Medicare Part B carriers and State Governments to recoup governments' funds paid in excess of reasonable costs from the providers and suppliers of the DEFENDANT DRUG MANUFACTURERS' pharamaceuticals; and the DEFENDANT DRUG MANUFACTURERS concealed from the UNITED STATES Medicare Part B carriers and State Governments an obligation of the providers and suppliers of the DEFENDANT DRUG MANUFACTURERS' pharmaceuticals to pay recoupment monies to the UNITED STATES and State Governments, resulting in great financial loss to the UNITED STATES and State Governments.

105. Because of the DEFENDANT DRUG MANUFACTURERS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of Two Billion Dollars ($2,000,000,000.00), all in violation of **31 U.S.C. §3729(a)(7)**.

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REQUESTS FOR RELIEF

WHEREFORE, Plaintiff, UNITED STATES, demands and requests that judgment be entered in its favor and against Defendants ABBOTT LABORATORIES; [redacted], on Counts I, II and III of the Complaint as follows:

1. On Count I (False Claims Act; Causing Presentation of False Claims) for triple the amount of the UNITED STATES' damages, plus civil penalties of TEN THOUSAND DOLLARS ($10,000.00) for each false claim;

2. On Count II (False Claims Act; Causing False Statements To Be Used To Get False Claims Paid By The GOVERNMENT) for triple the amount of UNITED STATES' damages plus civil penalties of TEN THOUSAND DOLLARS ($10,000.00) for each false statement;

3. On Count III (False Claims Act; causing False Statements To Be Used To conceal An Obligation To Pay Money To The GOVERNMENT) for triple the amount of the UNITED STATES' damages plus civil penalties of TEN THOUSAND DOLLARS ($10,000.00) for each false or fraudulent claim paid;

4. For all fees and costs of this civil action; and

5. For such other and further relief as the Court deems just and equitable.

Further, the Relator, VEN-A-CARE, on its behalf, requests that it receive thirty percent (30%) of the proceeds of this action or settlement of this action collected by the UNITED STATES, plus an amount for reasonable expenses incurred, plus reasonable attorneys' fees and costs of this action.

DEMAND FOR JURY TRIAL

A jury trial is demanded in this case.

Respectfully submitted,

Atlee W. Wampler, III
Florida Bar No. 311227

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Telephone (305) 577-0044
Fax (305) 577-8545

CASE NO._____

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 23d day of June, 1995, I caused an original and a copy of this Complaint to be filed under seal and in camera for sixty (60) days and not to be served on the Defendants named herein until order of this Honorable Court.

I HEREBY CERTIFY that on this 23d day of June, 1995, I caused a copy of this Complaint and written disclosure of substantially all material evidence and information the Relator, VEN-A-CARE possesses to be served on the Government pursuant to Rule 4(i), Fed.R.Civ.P., prior to the filing of this Complaint by delivering a copy of the Summons, Complaint, material evidence and information to the United States Attorney for the Southern District of Florida, and by sending a copy of the Summons, Complaint, material evidence and information by Certified Mail, Return Receipt Requested, to the Attorney General of the United States in Washington, D.C.

Respectfully submitted,

Atlee W. Wampler, III
Florida Bar No. 311227

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